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TITLE: Wrist Sensor for Warfighter Status Monitor Clinical and Field Testing Phase

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13. ABSTRACT (Maximum 200 Words) Twelve, versatile wrist worn pulse monitors were developed and delivered. A light, non-constricting band worn around the wrist is pneumatically coupled to a small electro-optical unit worn on the forearm. The forearm unit contains a fiber optic sensor, pulsed laser, photodiode, PIC processor, DSP, transceiver, antenna, memory, battery, and other parts. Physiological data is radioed to an RS-232 port on a standard IBM compatible computer. The computer switches the unit between two selectable modes; one streaming the 16-bit raw data at 512 Hertz and the other transmitting only the DSP processed heart and breathing rates. Algorithms are stored on the DSP via a standard computer cable. The DSP contains a wavelet algorithm, which aids in extracting data where there is excessive wrist motion present. It is likely that systolic and diastolic blood pressure and inspiratory effort could be extracted with a different algorithm. Subsystem components are activated only when needed, saving energy. Current drain is six milliamps if all subsystems are simultaneously activated. Re-chargeable coin cells allow about eight hours of continuous monitoring.				
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Forward

Empirical began working on wrist sensors because of a DARPA SBIR solicitation asking for new physiological monitors. Although many companies have attempted to build wrist monitors, which accessed the radial pulse, no progress was possible because of the sensors they used. These previous attempts at monitoring the pulse used piezo transducers, strain gages, and other pressure or force transducers. The problem with all of these is the force, which necessary for them to respond. When too much force is applied to the radial artery, the pulse either goes away or goes somewhere else. Empirical has invented, patented, and developed a sensor, which requires negligible force against the radial artery. These sensors also have negligible inertia and can follow the mechanical displacements of the pulse almost perfectly.

The original sensors proposed by Empirical were simple, common, bi-conically fused, single mode couplers. In this sensor configuration, we thermally fuse two optical fibers together, and then draw them lengthwise. Light injected into one of the fibers appears at its respective output. During the drawing process, the fibers neck down allowing the cores to get very close together. Once there is overlap in the fiber's evanescent fields, coupling occurs from the original fiber into the other fiber. After some further drawing, light appears equally on both output fibers and the coupler is completed. Straight couplers are physically secured to a substrate prior to handling. If the fused section is elastically displaced, the coupler output changes and the previously established balance is lost. Removal of the displacement force allows the coupler to return to its original balance. Any output ratio may be arranged, but the displacement of the fusion joint causes tensional stress because it must stretch to accommodate the displacement.

Empirical developed a way to secure the coupler inputs next to the outputs so that the fused coupler region becomes a freestanding loop. We arrange displacements in a looped coupler to be perpendicular to the plane of the loop, which results in almost no tensional strain. Further, the coupler sensor reduces in length by one-half and all the leads come out of one place. Originally, we potted these looped couplers in silicone rubber. Wrist sensors made with potted sensors were quite capable of monitoring the pulse in most situations. The sensors required careful placement over the radial pulse; however, rotation of the wrist caused the pulse to move, resulting in signal loss.

The next development used an unpotted coupler mounted against a diaphragm behind which is a liquid filled reservoir. The reservoir is also in contact with a compliant membrane, which is in contact with a large area surrounding the pulse point. The mechanical motion of the pulse pushes the fluid causing the membrane to bulge where the freestanding coupler is mounted. This technique was also successful and a full system constructed where all electronics, radio, and fiber optics integrate into a wristband. The wristband radioed breathing and heartbeat data to a remote computer.

In an effort to improve the sensitivity and with hypotension in mind, we abandoned this technique in favor of using air. The combination of using an air-filled balloon made of silicone rubber improved the system sensitivity to its highest observed value. The

silicone rubber balloon is made of a newly developed ten-durometer material giving it a very light touch. We attempted a number of prototypes before manufacturing six totally integrated wrist sensors. This sensor system wraps around the wrist as a unit containing battery, radio transceiver, fiber optic sensor, laser, photodiode, microprocessor, electronic circuits, valves, and small air pump operated by the thumb. The problem with this approach is the overall mass of all the components. The wristband's inertia opposes motions of the wrist and arm causing noise, which obscures the signal. For quiet use, the inertia is not a problem, but for other uses, this technique is not good. These wristbands were neither easy to position nor particularly comfortable.

The latest, final design eliminates nearly all of the inertia of the wristband by separating the electronics/sensor box from the wristband. The wristband only contains a light air bubble, pneumatically coupled to another bubble in the electronics/sensor box by a small tube. This design allows full rotation of the wrist while maintaining the pulse signal. The wrist sensor separation from the electronics/sensor box also allows use of the electronics/sensor box at other places on the body. Other bubble containing straps can monitor, for instance, the carotid artery, for possible diagnosis of rising intracranial pressure. Sensors work on the foot and many other places on the body. The bubble sensor strap is a very low cost, disposable element, while the sensor box is re-usable.

The electronics/sensor box contains a digital signal processor, microprocessor, fiber optic sensor, laser, photodiode, amplifiers, transceiver, battery, and a small built-in air pump. The box, about the size of a pack of cigarettes, transmits to a computer over distance of thirty feet. The computer can direct the box to send continuous, high-resolution data or pre-processed data such as the heart and breathing rates. Algorithms are unloadable to the DSP using a temporary hard-wired connection to the PC. Battery life is eight to sixteen hours and six units may operate in the same area without interference. The electronic circuit was designed and built by Invocon, Inc. of Woodlands, Texas. Invocon has developed highly innovative, low-energy consumption transceivers for NASA, DOE, and US Navy. Invocon went considerably beyond the original scope of the project and should share the success of this endeavor; their contributions cannot be over emphasized.

Based on other related work, Empirical believes the wrist units are capable of monitoring systolic and diastolic blood pressure on a beat-to-beat, ambulatory basis. Inspiratory effort is available from the blood pressure through measurement of the paradoxical pulse. Spin-offs from this program include asthma severity monitors especially for children, fetal heartbeat monitors, neonatal infant monitors, home apnea monitors for adults and children, SIDS monitors, digestive monitors, emergency medical and triage monitors, veterinary monitors, and others. A commercial license is in place and a development program begun. The sensor system has extremely good sensitivity at low frequencies all the way to the steady state. Varieties of non-medical applications are becoming apparent.

Table of Contents

Forward.....	1
Introduction.....	4
Body.....	9
Conclusions.....	22
References.....	23
Appendices.....	24

Technical Description of the Wrist Sensor System

Operation Manual for Wrist Sensor System

Introduction

Background

This introduction includes a broad summary of the sensor technology developed because of SBIR funding from the US Army. The basis for this developing technology is a special form of a single mode fiber optic evanescent wave coupler. The initial Phase I contract, which discovered this sensor form, allowed Empirical Technologies Corporation to explore many different applications than originally conceived. While the original Phase I contract only concerned obtaining a heartbeat signal, the Phase II led the way for applications to breathing signals, ambulatory blood pressure, and inspiratory effort, all detectable at the wrist. Further research and development of these signals continues through ongoing commercial and government contracts and grants. Future applications include monitoring of dehydration via inter-beat interval, determination of the circadian phase through ambulatory monitoring, and monitoring of existing or developing psychological conditions such as depression through ambulatory monitoring of the pulse rate.

Phase I SBIR results summary: DAMD17-96-C-6035

The purpose of this program was to demonstrate the feasibility of a fiber-optic coupler-based heartbeat and respiration sensor, which is compact and portable. The sensor device was a single mode fiber optic coupler whose coupling ratio was highly sensitive to small bending moments, such as caused by skin deflections due to pulse pressure. Photodiodes on each of the fiber coupler's two outputs measure the changes in the coupling ratio of the light traversing the couple. Electronic signals from the photodiode were recorded and analyzed.

The Phase I technical objective was to demonstrate a 'proof of principle' engineering model of ... a fiber optic sensor system for detection of various physiographic states or disorders, which are available through monitoring of the heartbeat, pulse, or breathing rate of personnel in critical situations. The physical parts of the system encompassed the sensor, the light source and its driver, the photodiodes and their supporting electronics, as well as a PC-based data logging software program.

Five tasks were outlined in the Statement of Work to develop and demonstrate the system capabilities. All five tasks were completed in the course of the program. Task 1 ("Coupler sensors will be constructed ...") involved the actual construction of fiber optic couplers and their implementation as sensors by mounting them in support frames of different geometries. Several designs were studied and the development of the sensor geometry over the course of the program was quite remarkable, resulting in a device of substantially reduced size, enhanced sensitivity and more rugged. Task 2 ("Transition to 1300 nm LEDs") was originally proposed due to the noticeably lower costs of operating at that wavelength, since both light sources and fiber can be obtained comparably cheaply due to the high production volume required by the communications industry. A noise analyses determined the tradeoffs of using LED versus laser sources in order to control

noise and enhance the signal to noise ratio in the very low frequency pass band appropriate for heart, breathing, and body motions. Task 3 ("Design and construct several Electronic Interface Units") involved the design, construction and testing of an electronic package consisting of an LED controller chip, photodiodes, as well as transimpedance amplifiers and an instrumentation amplifier to convert the optical signal and enhance the signal to noise ratio. A noise analysis on the design, and its performance showed characteristics in accordance with predictions. Task 4 ("Data logger interface ...") mainly involved the interface of a computer with the EIU through an analog/digital conversion board. A notebook computer was programmed in the Windows © environment to perform this task. Descriptions of the program as well as pertinent sections of the code are given. Radio transmission experiments tested the feasibility of transmitting signals from the sensor package to the logger. In the context of Task 5 ("Test of the heartbeat/respiration sensor"), we observed a number of data streams obtained from team members, demonstrating the capability of the fiber optic sensor to record heartbeat and respiration signals of high spectral purity. Spectral analysis using FFTs determined the spectral content of the signal, which in turn determined the digital acquisition rates and filter roll-offs in the electronic circuitry.

Phase II SBIR results summary: DAMD17-96-C-6035

The success of this program is evident in that a working telemetric wrist sensor was constructed and delivered. Specifically, the accomplishments of this program were

- To develop a generalized methodology enabling surface skin displacements due to pulse, whether due to heart beat or breathing, to be externalized for coupling to an extremely sensitive but also vulnerable fiber-optic coupler loop. The methodology is not limited to externalizing the radial arterial pulse but can be adapted to any body part that features pulse-related surface displacement, as evidenced by the concomitant development of a brachial and a chest sensor.
- A wavelet transform-based algorithm was developed and implemented on DSP hardware that verified the operation of the radial sensor during arm movement high-noise time sequences and permitted the extraction of the desired heartbeat signal from a noise background. While the algorithm's usefulness was clearly demonstrated, only extensive testing of the device will indicate whether further refinements are required.
- A wrist-worn micro-computer-based analysis and RF transmission system was designed and developed. The necessary operating system and control logic were developed and power conservation schemes implemented to give the system the capability to operate for several days on five AAA size batteries.
- The RF system was designed to operate within the general system originally proposed. As such, it was supposed to be able to radio the heartbeat and breathing rates to a belt or helmet-worn re-transmitter that would provide long-range transmission capability. In the context of that design, the present RF system was designed and tested for ranges of up to 20 feet. Future implementations of this system could feature longer-range RF electronics.

Patent: Patent: D. Gerdt, M. Baruch, C. Adkins, Variable Coupler Fiberoptic Sensor and Sensing Apparatus Using the Sensor, PCT 03-02-00 00011506

SIDS NIH Phase I summary:

Despite the recent reduction in SIDS after advocacy of the supine sleeping position, SIDS remains a major public health concern causing up to 5000 deaths per year, an incidence of 1 to 1.5 cases per 1000 live births. Home monitoring devices, however, are imperfect. To detect both respiration and heart rate, body straps with physical and electrical sensors are used. The strategy is to detect such episodes of bradycardia and apnea at their inception, and then to physically arouse the child. The problems with this approach include expense, unreliability of skin contact and limitation of infant activity. The proposed fiber optic sensor pad provides an ideal way of measuring heart and respiration rates using a totally dielectric pad and tether fitting under the bed sheet. Analysis algorithms for detecting abnormal bradycardia and apnea will be implemented. The specific use intended is a mattress pad for a premature infant, during hospitalization and after discharge. Since the fiber optic pad is completely safe and relatively inexpensive its usefulness extends to emergency medical services, inpatient, and outpatient monitoring of adults with known or suspected heart disease

Patent: D. Gerdt, M. Baruch, C. Adkins, Sensing Pad Assembly
Employing Variable Coupler Fiberoptic Sensor, PCT 03-02-00 00010447

Asthma NIH Phase I summary:

A cuff-less device for the non-invasive measurement of blood pressure (BP) and pulsus paradoxus is proposed. The device utilizes two identical fiber-optic pulse sensors that, applied to an extremity at a known distance apart, measure the delay in arterial pulse propagation. This delay correlated with systolic blood pressure and with the impact that breathing has upon blood pressure, that is, pulsus paradoxus. This project will demonstrate that pulsus paradoxus can be accurately measured and monitored in a proof-of-concept-testing design.

A need exists to develop a non-invasive and effort independent measure of asthma severity that can be deployed to pre-hospital care and emergency department personnel. Pulsus paradoxus is a pathological vital sign which shares these features and has previously been recommended in NHBLI Asthma Management Guidelines. Historically the measurement of pulsus paradoxus was performed via sphygmomanometry which has recently been shown to be inaccurate. By contrast, the proposed fiber-optic sensor system provides the capability to monitor and quantify non-invasive measurements of pulsus paradoxus.

Patent: M. Baruch, C. Adkins, D. Gerdt, Apparatus and Method for
Measuring Pulse Transit Time, PCT 03-02-00 00010453

Phase II Quality Award

Originality and innovation: The Phase II award to ETC required a wrist sensor unit which would, when RF queried, send back two numbers, heart rate, HR, and respiration rate, RR. This highly innovative concept developed at MRMC was recently demonstrated through SBIR funding to Empirical Technologies Corporation, ETC. The demonstration verified a means to save the lives of soldiers and also led to an unexpected bonus, a simple method for ambulatory blood pressure monitoring. The Phase I statement of work caused Empirical Technologies Corporation, ETC, to invent and file a patent on a new type of fiber optic coupler sensor which, through light and gentle contact with the radial pulse palpation area, measures HR and RR. ETC, through a series of engineering innovations, combined this sensor with a laser diode source, photodiode, amplifiers, digital signal processor with embedded wavelet extraction software, electronic housekeeping functions, radio receiver/ transmitter, and batteries. A wavelet transform was developed which allows for extraction of HR and RR even while the arm is undergoing rapid motions. The Phase I work towards a physiological status monitor further led to a Phase II demonstration of a simple, highly innovative BP monitoring system which does not currently exist in any commercial form, yet is vitally needed for military and commercial uses.

Relevance to the army and its mission: During times of armed military conflict, there are medical rescue attempts, which result in injury or death to the medic. Many of these valiant attempts are later found to be unnecessary because the soldier is stable, requiring no immediate attention, or already dead. A remote physiological status monitor, providing HR and RR would generally suffice for indications of patient condition. Personal risk is thereby minimized for the medic and unit readiness is conserved. With the addition of a second sensor blood pressure, BP, can be determined in various extremities. BP is important triage information, which allows for maximizing the effectiveness of medical support. Of all the vital signs, BP is probably the most important. In addition to calculating the BP every heartbeat cycle, another important parameter may be measured, the pulsus paradoxus, PP. PP is the drop in BP during inspiration and is a measure of respiratory effort. Respiratory effort would be an indicator of breathing difficulties associated with gas attacks or plural puncture wounds. There is some indication that proper monitoring of the carotid pulse could measure rising intra-cranial pressure due to head trauma, the second leading cause of combat related death after exsanguination. Additional information may be available due to the remarkable low frequency characteristics of the sensor. Dehydration, general alertness and sleep may be measured at the wrist with further pulse analysis. If circadian phase can be monitored with a wrist sensor, then it is possible to schedule land and air operations with peak alertness.

Commercialization into marketplace: No commercial monitors are sold which measure BP without discomfort or pain. No commercial BP monitors allow sleep. Although the noninvasive pulse velocity method is an old technique, satisfactory demonstrations have been elusive. This new technology allows introduction of a simple and comfortable BP monitor into many medical environments. These environments include emergency

medical, intensive care, and outpatient care. PP was as a hospital admission standard for asthmatics, but later abandoned because physicians cannot accurately measure it with current technology. The combination of an ETC wrist sensor and brachial sensor measures PP every breathing cycle. There is no system, which can do this comfortably and accurately. Together, the BP and PP can diagnose sleep disorders such as obstructive sleep apnea. Presently only polysomnography can accomplish this, which requires a night's stay in a hospital. The radial/brachial sensor BP system will allow home monitoring for sleep apnea and testing of treatment strategies for control of apnea.

Project Awards: ETC received an Outstanding Achievement Award from Governor Gilmore in 1998 for work towards the "Wrist Sensor for Warfighter Status Monitor". Virginia's Center for Innovative Technology selected the wrist sensor technology for an Innovation Award, which will provide \$25,000 to UVA for further circuit design. ETC's sensor technology was selected as one of 15 non-pharmaceutical medical device technologies for 1998 by BTG International Inc. BTG is a global leader in patenting and marketing intellectual property rights (IPR) for technologies that shape the future. BTG acquires, develops and licenses IPR covering innovative products and processes in the fields of electronics & telecommunications, biosciences and medical & physical sciences.

Award Qualification Statement: The wrist sensor is capable of saving the lives of medical research personnel, thereby preserving readiness. Historically, about 20% of medics killed in action are attempting to reach personnel who are already dead. By instituting remote physiological monitoring, this number should to reduce to less than 5 %. The development of simple BP monitoring equipment will contribute to large advances in combat casualty care in terms of triage, ambulatory monitoring, and interfacing with new infusion pump technologies. Ambulatory BP technology will touch almost every citizen sometime in life. ETC's BP system is not annoying or painful and allows sleep, advantages which no current system can claim. With over 10 % of the national population suffering some form of sleep apnea and the recent correlations with automobile accidents, stroke, high BP, and heart disease, the diagnosis and management of apnea is becoming very important.

Empirical believes that the proposed system will allow maximum flexibility so that the most desirable set of physiological parameters measured. Knowledge of these parameters, while being vitally important to the military, would also be useful for firefighters, emergency rescue triage, chemical/biological clean-up, and athletic conditioning. Other uses extend to health care in hospitals, clinics, and home monitoring.

Body

The goals of the contract are listed below. Each original goal is listed following a "➤" mark. Comments concerning the goals are in italicized text following each goal. The comments are intended to summarize how the goal was reached or why the goal was not reached or how a goal was modified.

Goals of this contract: DAMD17-00-C-0017

- Each wrist unit will be reduced in size and contain a flat pack battery and transceiver unit. All circuitry will be on a board about the size of a nickel. *Flat pack batteries are not available in small quantities, although we did manage to get a few samples. Instead, rechargeable button batteries were used. These were small, relatively light, and provided adequate current for eight hours of continuous operation.*
- The flat pack battery will provide about 120 mA Hr @ 3.2 V. The flat pack battery is rechargeable and will be inside the lid of the wrist sensor for easy replacement. They are rechargeable for more than 500 times. *The button batteries used instead of the flat pack batteries are rechargeable more than 500 times. Replacement of the button pack requires some disassembly of the unit.*
- There will be no unit above the wrist as used in the Phase II feasibility unit, only a wrist unit smaller than the current unit below the wrist. *The electronic/optical/control unit could not be reduced in size enough so that this unit could be part of the wristband. Early in the program, we agreed to provide for a sampling rate of 512 Hertz, far above our original goals. Additionally, a resolution of 16 bits, as opposed to 12, was required in order to provide highly accurate pulse waveforms.*
- The new transceiver's microprocessor consumes at 18 μ A @ 3 V (4 MHz). The current design takes many mA @ 6 V (33 MHz). Processing is still possible at 4 MHz, but it might take another ten or twenty seconds as opposed to 33 MHz. The data processing is meant to be performed on the intermediate or belt unit. *The belt unit was eliminated in an early program meeting in favor of on-board processing. The onboard processing occurs on command from the base station at the PC. A programmable Digital Signal Processor (DSP) is included with the electronic/optical/control unit.*
- The antenna will be located flat on the transceiver board, fitting within the nickel boundary constraint. *The antenna was kept as a flying wire in order to increase the range to about 30 feet.*
- The data rate out of the wrist sensor may be software selectable from the base unit through the network to be between 1 and 10 K bits/sec, perhaps higher. *The data rate in continuous mode is set to 512 Hertz because implementing selectable data rates would have added significant*

complexity to the system.

- The network, intermediate (belt units)/relays/base units will operate at 121 K bits/second. *The belt units were eliminated at an early program meeting. Instead, a PC interface unit was supplied with each sensor package.*
- Although the base unit may only address one sensor at a time, it will be able to address each one fast enough so that the monitoring appears continuous. This might be the case where the entire waveform is passed through the network for observation and/or logging. *It is possible to operate as many as six sensors in the same area and still receive the full 512 Hertz sampling rate from a selected sensor.*
- The belt/wrist units will be RF programmable to operate autonomously for longer term observations, for example, to take data every ten minutes for three days, store the heart rate, breathing rate, or others for later downloading and analysis. *The DSP residing in the wrist sensor may be programmed as stated above except that the programming cannot be through the RF link. Programming the DSP is through a direct PC link.*
- The base station will allow re-programming, through the network, of each or all of the sensors under its control. Changes might include data rate, algorithm changes or new algorithms. *The base station can re-program the DSP, but only through a direct PC link.*
- The present "keep alive" circuit requires 4 mA continuous operation which is large and limits the number of "hits". A new design will be implemented lowering this value to 0.75 μ A, effectively zero. The transceiver uses 6 mA but is only on for a few μ sec., effectively zero in the old and new designs. Now, only the laser diode is responsible for operational duration. Indications are that the laser's duty cycle can be cut in half and perhaps reduced to 1 % of the present value, dramatically increasing operational duration. *In idle mode, the unit uses less than one mA. In other modes, the use is closer to six mA. The laser diode is pulsed. This results in an average current drain of less than one mA. A continuously operated, high efficiency laser draws over 18-20 mA.*

The contract was to build basic prototypes: clinical prototypes and field prototypes. It was also necessary to develop several interim prototypes.

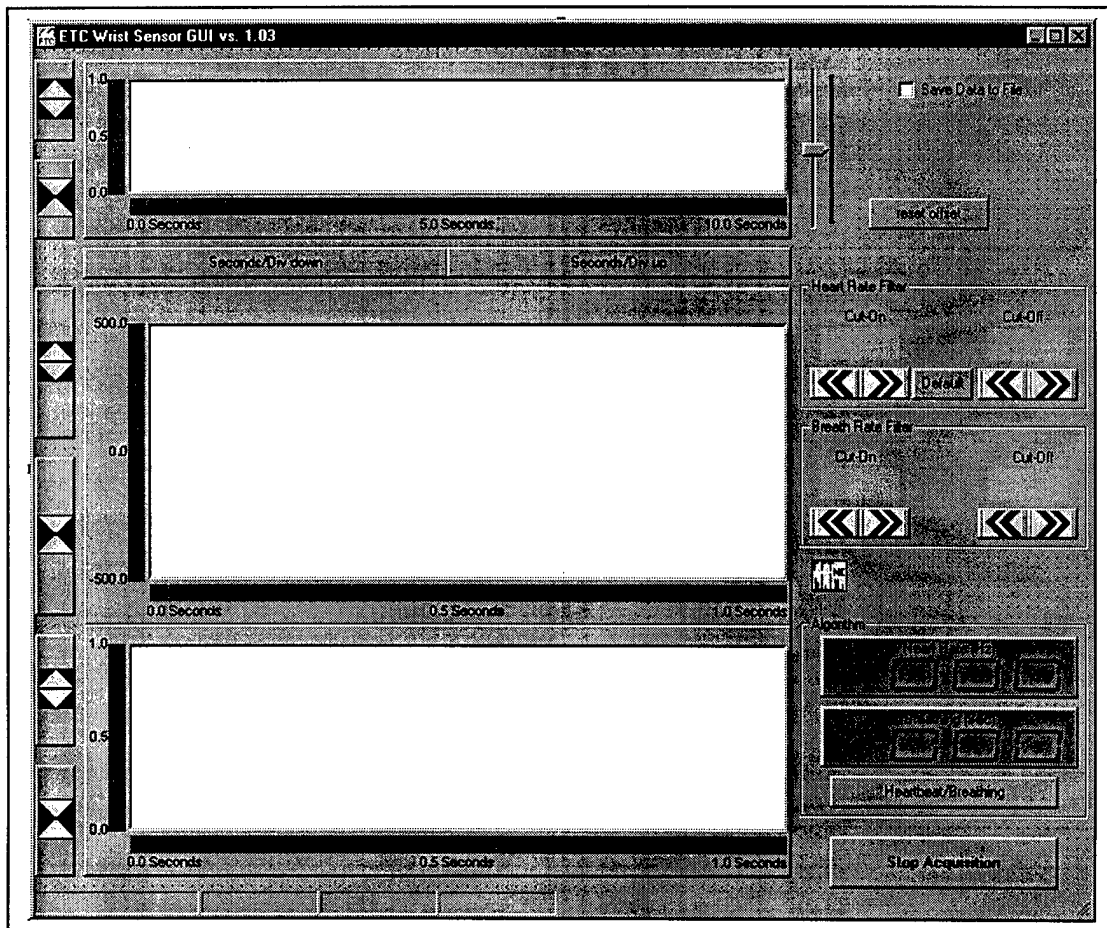
Discussion of the Clinical Prototype Units:

Clinical units stream data to an RS-232 enabled receiver. Signal processing occurs at a remote, RF-linked, data collection site. The Clinical units cannot process pulse data on-board.

Clinical Unit Radio Transceiver: The operational frequency uses a 916.5MHz narrow band RF transceiver operating at a raw data rate of 250Kbps. The wrist unit and forearm

unit transmits (streams) data to a nearby PC at 512 Hertz with 16-bit resolution. In these first prototypes, all algorithm development or other analyses occur at the PC and no calculations occur in the wrist unit. The intended prototype board originally has dimensions of about 1 inch X 1 inch X ~3/16 inch thick. Unfortunately, this board only supported 12-bit resolution and much lower data rates. In order to provide the 512 Hz data rate and 16-bit resolution, a larger board resulted. The dimensions of this new design are 1.61" X 1.37" X 0.28". This board, while larger, broadly expands the capabilities of the original board.

The clinical units use a new GUI, which allows real-time frequency filtering of the received data. The GUI (see below) allows visualization of the raw signal and two filtered bands, which are user selectable. In practice, we have used one to capture the fundamental signal from the heartbeat signal and the other for capture of the fundamental signal from the breathing signal.



The dual filter capability solved a problem related to the DC signal. An early problem due to the large dynamic range of the sensor was because the DC contribution is very large and the AC contribution is relatively small. The reason why the system had to evolve to 16 bits was to insure that there would be plenty of dynamic range for the heartbeat signal after allowing for the potential swing of the DC component.

The resulting GUI development allows the near real-time viewing of any signal band as an AC component. The heartbeat typically lags the display by four seconds, while the breathing signal lags by 16 seconds. The lags are necessary because the signals are of very low frequency and therefore require adequate sampling time. This approach takes all filtering requirements off the electrical side of the board. While it is possible to make electronic band pass filters for virtually any frequency band, it is not so simple to do this at the very low frequencies necessary for breathing and heartbeat because they are so close together. In simple RC filters, the capacitors get very large physically. Electronic filters, even complex types, are not really too distinct, that is, they roll on and off rather gently. The advantage of using software programmable FFT filters is that they are, for all practical purposes, infinitely steep when compared to any other filtering method whether hardware or software. The resulting GUI, which is based on software FFT filtering, is a system, which can nearly perfectly select out two distinct bands of interest, allows full visualization of an AC signal always centered on the GUI window, and, most importantly, allows independent amplification of channels.

One interesting observation comes about when the heartbeat signal is filtered to exclude the fundamental, but include only the first harmonic. The resulting signal is very good-looking heartbeat signal showing the dicrotic notch and other features associated with the fundamental. It known that impulse functions such as the heartbeat pulse have energy content primarily at the fundamental. A power spectrum of an impulse function decays rapidly after the first few harmonics. This result implies that we need only amplify the signal band of interest for all the necessary information.

Battery Requirements of the Clinical Units: The clinical units use three NiMH rechargeable cells, which provide for 24 hours of continuous operation. At low temperatures, re-chargeable batteries are significantly de-rated and may not be the best choice in a fielded unit. An alternative is to use ordinary batteries where very powerful batteries are available among the Lithium varieties. Because these units are prototypes intended for experimental use, rechargeable batteries are the best choice.

The cells are uniformly distributed around the band, as are the remaining components. This distribution balances the band while also making it thinner. Unfortunately, the mass, while distributed, was still very large, making the wristbands very susceptible to small wrist motions. Field unit prototypes avoided this problem by using a very light wristband pneumatically coupled to a sensor mounted on the forearm.

The clinical unit communicates with a nearby transceiver attached to a PC. There were six clinical units delivered. The design allows at least six units to operate simultaneously within the same general area. The system can continuously on its own battery power for at least 24 hours. The wrist unit wraps itself around the wrist and forearm. All electronic and optical parts are within one wrist unit. The clinical designs abandoned fluids in favor of air. We found that air provides a much better transmission of pulse displacements than water or some other hydraulic fluid.

Discussion of the Field Prototypes

Field units, in contrast to clinical units, have on-board signal processing of pulse information in order to extract various physiological parameters. After extraction, the heart and breathing rates numbers transmit via radio to the PC. Additionally, the field units have may be switched into "clinical unit" performance via radio telemetry commands from the PC. DSP algorithms are uploaded from a PC to the Field units via a serial data cable. Re-programming the DSP, via RF command, is not possible. The re-programming of algorithms via radio is problematic because of the chance for a transmission error, which would likely lock-up the system. For this reason, hardwired programming was adopted instead of RF programming. Algorithms, uploaded from the PC, are stored in the internal memory of the field units in machine language.

The firmware allows the system to stream data to the PC at the full data rate of 512 samples per second. The firmware is a write-once, read-many (WORM) type of memory, which resides on the microprocessor. From the standpoint of algorithm development, it is better to use the streaming mode until algorithms are fully tested and developed. This way, development occurs in a PC environment rather than a machine language environment, which is required for the microprocessor on the wrist. PCs support high level languages and multitudes of canned programs, which allow for efficient searching for algorithms and easy changes. Once useful algorithms are found, the successful algorithms can be coded for the wrist sensor processor.

The field units provide a useful dynamic range of nearly 16 bits. The instrumentation front end (interface to the optical sensor) was implemented as a trans-impedance device. The 16-bit design allows more than 12-bit resolution of the pulse signal and passes much lower frequencies as well. As there is now no low frequency cut on, the frequency range is $\ll 0.1$ Hz. This system property greatly expands the usefulness of the system since additional physiological parameters characterizing the parasympathetic and sympathetic nervous systems could be available.

Field Unit Radio Transceiver: The radio for the field units is identical to the radio in the clinical units.

Battery: The coin cell re-chargable battery will provide about 80 mA Hr @ 3.2 V. The battery is rechargeable and is inside the case of the wrist sensor. They are rechargeable for more than 500 times.

The field unit batteries may be different. If we use a flat pack battery, the volume may be $26 \times 34 \times 1 \text{ mm} = 884 \text{ mm}^3$ or smaller. A flat pack battery would last for about one 24-hour day of continuous use (where the data is streamed out). If the wrist sensor were used in a query mode, where about 35 seconds are required to take and either store or transmit two numbers, then the number of "hits" would be about 2500.

Two pairs of flat pack re-chargeable batteries were received from Battery Engineering, Inc. They are both too large for a field wrist unit, although one is close. The technology of polymer solid-state lithium batteries is progressing rapidly due to the demand for re-chargeable phones and other wireless devices. These batteries are difficult to obtain especially in packages to suit our application.

Battery charger: The charger is designed to recharge the VARTA 3/V80 Ni MH batteries used in the Warfighter wrist sensor in a minimal time. The charger is limited to a maximum initial rate of charge of 0.5C Amps (a three-hour rate) and is self-regulated to gradually reduce the rate to about 0.01C Amps, which will sustain indefinitely.

The charger uses a conventional NPN pass transistor to regulate the charge into the battery pack. A 6.2 Zener establishes a fixed reference from which a stable base bias for the 2N2222A is derived. As the battery voltage increases, the forward base-emitter drop reduces until at full charge, the junction is reverse biased and the transistor goes into cutoff. As the battery self discharges, its voltage drops and a small trickle current is established which will maintain the battery indefinitely.

Size of the circuitry: The unit was tested for its ability to stream 512 Hz data, a rather high data rate and one well above Invocon's normal rates. This high data rate represents a significant accomplishment, which greatly improves the usefulness of the units. The 512 Hz requirement was requested as a system alteration at a previous status review meeting.

There are two circuit cards in the final system. The first of these is what IVC is calls the "network" card (for lack of another name). This card houses the following functions:

- (1) Network Protocol Management
- (2) Message formatting and de-formatting
- (3) Error detection and correction processing
- (4) Communications of data as well as commands and acknowledgments
- (5) Modulation and demodulation control of RF carrier signals
- (6) Control of the radio for transmit and receive states
- (7) Calculation of link quality estimates
- (8) Synchronization needed for RF transmission
- (9) Memory hardware and memory management for the system
- (10) Calculations of network data for control purposes
- (11) Calculation of system data for compression purposes
- (12) Supervision of DSP algorithm execution
- (13) Supervision of data flow to DSP for processing
- (14) Serial port to PC for debug and possible data exchange with external PC
- (15) Communications with GUI/PC
- (16) System priority-interrupt structure
- (17) Internal system power management
- (18) Transducer power-supply and power control

The second card (DSP/Data Card) contains the DSP and signal input circuits:

- (1) Input signal conditioning - filtering and gain.
- (2) A/D conversion
- (3) Interface with the network card for signal synchronization
- (4) A/D data exchange protocol with network board
- (5) DSP circuits and interface with the network board
- (6) Means by which data can flow from memory on the Net card to the DSP and back to the net card for processing
- (7) Power control for the DSP circuits so that the DSP can be shut down while data input is in progress
- (8) Power control for the analog section for power savings.

The second card has two major schematic elements. The first is the DSP and associated power and data control circuits and the second is the signal acquisition, conditioning, analog to digital conversion capability and power control. The final plan involved using much wider range A/D conversion circuit, 16-bit, that had sufficient resolution to represent even the smallest signals. There may be a significant advantage to using an A/D of about 24-bit resolution where extremely weak signals are required for detection. The 16-bit A/D units were not available when we started the program, but implemented by Invocon. This implementation made a significant difference in the versatility of the units.

Layout of the wristband and sensor system: It was clear from using the clinical units that the inertia of the wrist band was most important. The best signals were obtained with wristbands, which were very light. Because the circuits and battery are relatively massive even in miniaturized form, the electronics/sensor unit was separated from the wristband. We found that the best configuration consisted in a wrist band, which contained a small bubble of silicone rubber. The volume of this bubble connects to another bubble of silicone rubber in the electronics housing away from the wristband through a small piece of tubing. To inflate the bubbles, a small finger pump has been placed on the side of the electronics/sensor unit. With this separation, the wristband is very light and works very well. The wristband may also be considered a disposable or replaceable element. The electronics/sensor unit is where all the expense resides. The electronics/sensor unit is encased in a case and well protected. There is another advantage to this layout. The wristband bubble can detect the pulse at many other palpation points on the body. However, the bubble would be enclosed in a different housing if it is meant to detect pulse at the foot or neck. This way, one sensor/electronics box could be used to mate with a variety of pulse sensors working at different places on the body. We are fairly confident that systolic and diastolic blood pressure may be obtained from the pulse signal. This allows ambulatory monitoring of BP, HR, and RR at many places on the body.

Power requirements of the circuit: The new transceiver's microprocessor consumes at 18 μA @ 3 V (4 MHz). The current design takes many mA @ 6 V (33 MHz). Processing

is still possible at 4 MHz, but it might take another ten or twenty seconds as opposed to 33 MHz. The data processing is meant to be performed on the intermediate or belt unit.

The pulsed laser diode technique: Invocon has provided for pulsing in their processor. Presently, this processor takes 132 μ sec per read cycle. Since there are 512 reads per second, the laser need be on for only $132 \times 512 = .068$ seconds. This brings the current dissipation of the laser down from 18 mA to 1.2 mA, a significant reduction. Reading cycle time could be reduced further.

Antenna: The antenna consists of a wire, which sticks out of the electronics/sensor box. We had originally planned a very short transmission range, about two meters. This could be accomplished using a small flat spiral antenna. Instead, since more range was desirable, we used a more efficient wire antenna, a flying wire.

Network: The network was abandoned in favor of PC based receivers, on-board processing, and higher data rates.

Base station unit: The PC is the base station for the field units. The field units will operate in several modes, streaming data, streaming processed data such as heart and breathing rates, and sleep (data on demand). As the units are programmable, they are configurable to report processed data at desired time intervals.

General volume reduction: The units will be smallest when all major parts occupy minimum volume. This analysis does not consider the volume of tiny wires or tiny fibers, which connect the major parts.

Glass splices occupying 450 mm³ each can be reduced by fusion splicing to 10 mm³. Two or three are required in the final design. Fusion splices require protective sleeves, which can be very small for the newer fusion splicers, but are about the same size as the glass splices for our fusion splicer. Another reason for not using fusion splicing in the final units was due to the large circuit, which accommodated the 512 Hz sampling rate at 16-bit resolution.

A reduction in the sensor size amounts to about 20%. We did succeed in reducing the sensor size by about this amount.

Other major parts are listed below:

<u>Major Part</u>	<u>Volume (mm³)</u>	<u>Current consumption (mA)</u>
Electronic unit	3075	. 02 or 6*
Batteries	4000 or 884	none
Laser diode (see note)	40	1

Photodiode (1 or 2)**	40 or 80	none
Sensor	760	none
Splices (2 or 3)**	20 or 30	none

* If the unit is in sleep mode, the current consumption is < 0.02 mA. When the DSP is fully on, the current consumption is 6 mA. When the unit is transmitting, 7mA are necessary, but only for a few msec.

** One or two photodiodes may be used on the wrist sensor. Two increase the sensitivity, which is important in hypotension.

Options for reduced energy consumption: We were successful in eliminating the large current drains necessary for laser diode operation. Previously, the laser was on continuously drawing 18 to 20 mA. As the microprocessor only sampled the sensor output for a few milliseconds, we attempted to pulse the laser in synchronization with the data sampling. This resulted in reducing the effective continuous current drain to less than one mA.

Options for fiber optical sources: A search for lower current laser diodes revealed a variety of sources. Relatively inexpensive, high manufacturing volume sources are being developed in Japan, but except for data sheets; the actual products are not available. DARPA sponsored a program in St. Louis about two years ago, which was reported to result in very inexpensive packages for pigtailed laser diodes, five dollars in production.

The DARPA program did result in a MOEMS (micro-opto-electro-mechanical system) design for a three-dimensional fiber alignment tool. The company, which ended up fabricating these devices, was CRONOS. Chris Sanders (Phone: 914-248-4132) was familiar with the project, which ended three years ago. There are no devices available, but a production run is available for about \$150,000. This would produce 25, 8" wafers containing about 5,000 devices. The MOEMS devices would then be sent to a company where laser diode modules and fibers are attached. In larger volumes, the price should to fall to about \$10 per final copy.

Another way to replace the 800 mm³ package uses silicon v-grove technology. Silicon wafers can be differentially etched so that extremely precise v-groves result. AXTI Fiberoptics of Monterey Park, CA uses this technology to pigtail diode lasers operating at red wavelengths. They also use 1300 nm laser diode dies occupying 0.250 X 0.250 X 0.110 mm³ (0.007 mm³). The silicon v-grove piece is somewhat larger. AXTI has never pigtailed their 1300 nm laser diode dies, but said they would for us. In the end, these devices could not be obtained as samples or purchased parts. Volume is the key to obtaining these devices. The final cost of these pigtailed devices is projected at <\$10 in large quantities (thousands). This package, although very exposed, is potted in an optical grade silicone rubber making the package quite robust.

It appears that we may have to stay with our present laser diode package, which occupies about 800 mm^3 . The technology is available to reach a volume of one mm^3 . This package may be reached in two ways, neither one of which is easily available in the near term. We will continue to monitor developments in pigtailed laser diode miniaturization.

Two very small, pigtailed photodiodes were purchased from Fermionics Corp. They are adequate for the miniaturized field units. We ordered two of these pigtailed photodiodes and reduced the volume of these components from 800 mm^3 to 40 mm^3 each. They were not used in the final design because of they were expensive and hard to get. Since the laser could not be reduced in size, it was not useful to reduce the photodiode.

Another space saving option was explored. This option uses silicon "V"-grove technology to attach the sensor fibers directly to the laser and photodiodes. We were unable to obtain samples of the 1310 nm laser diodes mounted on a silicon carrier substrate. AXTI Fiberoptics makes these devices at other wavelengths and are willing to supply ETC with samples operating at 1310 nm.

The v-grove technology will not be available to us for some time. By combining the v-grove technology, mounting the laser and photodiode on the size-reduced sensor substrate, reducing the battery volume, and hybridizing the circuit the resulting package will be more the size of a standard large wristwatch. We cannot hybridize the circuits, as the price is quite high, about \$65K or more. Flip chip technology may be even better as far as reducing volume, but not much different in cost. Another option was pursued which separates the sensor bubble from everything else via a pneumatic tube allowing the bubble to be on the bottom of the wrist and all the sensor/optics/electronics to be located on the top of the wrist.

ETC was successful in making a smaller sensor loop than has been previously available. This resulted in approximately 20% less volume. We built a special furnace, which is much narrower than the standard furnace. This furnace allows shorter couplers to be drawn and reduces the length of the loop making shorter, smaller sensors.

Further increases in sensitivity: The final design showed that a pulsed laser diode provides a full reproduction of the pulse waveform. Invocon provided for pulse timing in their processor and ancillary electronics. In the final design, the laser diode is pulsed at its normal current level. Pulsing the sensor at higher than normal current levels, which is within the operational parameters of the laser diode, could provide much more light during the measurement interval and, consequently, would result in a lowered shot noise floor, allowing for more amplification of weak signals. We did not pulse the laser diode at larger than the normal operational current level because of the impacts on the photodiode gain, which we had adjusted to a very stable level. The primary reason, however, for not increasing the pulsed current level is that we cannot presently use more dynamic range. We are fully using most of the 16-bit available by the A/D. If further increases were sought, we would need to increase the resolution of the A/D converter to beyond 16-bit. Such A/Ds do exist, but not in a low power configuration, which is

required for our application. 16-bit resolution appears to give us all the sensitivity we can realistically use at this time.

The preliminary Invocon design allowed both outputs of the sensor to be used. The use of both channels provides a four times improvement in signal to noise levels because the signals are complimentary. Complimentary signals can be divided for a ratio determination, which has the advantage of dividing out much of the common mode (intensity) noise. The use of both outputs necessitates the use of another photodiode and A/D. We are already using the full 16-bit resolution of the processor and so this complication was deemed not useful without a change to a higher resolution A/D.

Additionally, the use of a reference coupler, which tracks wavelength wander, can further reduce the phase noise. The reduction of phase noise further complicates the optical and electrical circuits because two more channels are needed along with signal processing to subtract out the phase noise contributions. Due to the complexity of the final circuit, which was re-designed to accommodate the high sampling rate (512 Hz) and a higher resolution (16-bit as opposed to 12-bit) only one channel is used. Again, at this point, we cannot use more resolution because we are already fully using the 16-bit A/D.

Other modest improvements in s/n may be available, but other large increases are not expected. The present sampling rate and resolution provides much more high quality data than has been available in any non-invasive sensor. Moreover, the "quality" level of signal is largely unexplored at present. Until the limits of this present system are known, there is little point in forging ahead for the sake of still higher resolution.

The wristband: In the field units, all the system components except one are located in an external housing located near the wristband. The external housing encloses the sensor and all electronic and electro-optical components. The wristband attaches to the housing by a pneumatic tube. A very soft silicone rubber pillow is part of the wristband and contacts an area at the wrist where the radial artery resides. The pillow is inflated to pressure of about ten inches of water and palpates the pulse. The inflated bubble insures uniform contact with the radial artery area. The artery moves around as the wrist moves so the contact area of the bubble must be large enough to accommodate these different positions. Velcro straps on the wristband allow securing to the wrist.

The air volume of the wristband pillow connects to another pillow-like bubble in the external housing silicone rubber tube. The wrist sensor loop rides on this bubble of very flexible silicone rubber. The pillow in the wristband and bubble in the housing are both made of a very low durometer silicone rubber, about ten, Shore A. A small manual air pump on the side of the housing inflates the pillow and bubble.

There are several advantages of this method:

- The wristband has low mass and therefore low inertia. A heavy wristband is problematic because of its inertia. As the wrist moves during exercise, the inertia of the wristband fights the movement of the arm adding motion-induced noise to

the system. The wristband only contains a silicone bubble, which makes contact with the wrist.

- The silicone bubble connects to the component box by a small silicone tube. The pulses sensed at the wrist transmit to the external box pneumatically. The bubble under the sensor can be large and sensitivity has increases noticeably.
- All crucial components are contained in a protective enclosure.
- It is simple to change out different wristbands since there is only a tubing fitting and a tube to be connected.
- The only system part, which could easily break, is the wristband. The wristband is a simple part considered disposable. The disposability is useful for right and left-handed versions or for attachment to other parts of the body.
- It does not seem to matter if the connecting tubing ID is large or small. The air column between the two bubbles seems to act as a piston and the air seems to act as a perfect fluid. Operation, the radial artery pushes against the bubble, which pushes the air column as a unit into the bubble where the fiber optic sensor is located. The air column does not compress, but simply moves the air column as a unit. This situation would not work for a fluid such as water, which is about 1000 times as dense and has 1000 times the inertia. Using water, the artery would simply push out somewhere else and no signal would get into the column. It is the very low inertia of air, which allows the transfer of the palpation of the artery to a palpation of a bubble located at the fiber optic sensor inside the protective enclosure. Several other factors are important. The velocity is very low, which leads to essentially no viscosity or frictional loss and no turbulence. If the air column were a real fluid, it would have to obey Poiseuille's law and the flow resistance would be very dependent on the ID of the tubing, which, by observation, it is not. The resistance to flow should also be linearly dependent on the viscosity and the length of the tubing. The length seems to have little effect and the viscosity of air is very low. It appears that the air column acts as an incompressible piston with almost no inertia.
- This design allows bubbles to be located in a band-aid for attachment to other parts of the body, yet keeps the expensive components reusable. The technique would allow for a quick placement of a sensor on the carotid or pedal palpation sites. Two of these could provide very quick assessment of blood pressure for instance using the pulse transit time. If one were already on the wrist, then only one additional would be required.
- The optimum size of the bubble in the wristband is about one inch in diameter. This size is the minimum size, which allows physical contact with the radial artery as the wrist moves through a full range of motion.
- The size of the bubble at the sensor cannot be too small otherwise; a great deal of force is required to move the bubble membrane against the fiber optic sensor. If the bubble is too large, then most of the movement goes against elastic stretching of the bubble and not into motion, which is picked up by the fiber optic sensor. From trial and error, using material obtained from Rogers Corporation, we found the optimal diameter is $\frac{1}{2}$ to $\frac{7}{16}$ inch. This results in a mechanical advantage of three or four to one since the diameter of the wrist sensor is 1 inch and this factor increases sensitivity proportionally. The Rogers material is uniform and

consistent. Another vendor's material with the same specifications was inconsistent, non-uniform, and unpredictable.

- The sensor is able to sense the radial pulse regardless of the position of the hand. This is because the bubble is large and allows palpation no matter where the pulse moves during hand movement.

Memory options: It appears that flash memory is small enough and low power enough to allow storage of several days ambulatory pulse in a small space. The hardware requirements may require something the size of a cigarette package or more. If there were room on the belt or somewhere else, this approach is feasible. Very little energy is required to record data in a flash format; however, the clearing of this format is very energy intensive. Although the present units designed to connect to a PC through the RS-232 port, a high-end palmtop with a flash memory card is capable of storing all the necessary data for one or more days of continuous use. At present, the software does not exist to interface the RF data to a palmtop. The software may not be too difficult as high-end palmtops are very sophisticated.

Conclusions

Empirical has produced a new and versatile ambulatory physiological monitor. The key element of this system is a novel fiber optic displacement sensor, which provides characteristics not available through any current sensor technology. The wrist sensor system, designed around this optical sensor, represents the beginning of a family of personal and personnel physiological monitoring systems. The wrist units communicate via radio to a personal computer. The wrist sensor has sufficient memory and processing on-board to allow a variety of applications, for example extracting heart rate every minute, storing these values for ten hours, radioing a problem to a nearby PC or PDA that calls an ambulance. As a platform, the full potential of this system remains mostly unknown. We know that heartbeat and respiratory waveforms are obtainable remotely from any pulse palpation point on the body. It is fairly certain that from these same points, systolic and diastolic blood pressure is obtainable on a beat-by-beat basis. The sensor is both non-restricting and non-squeezing. It is comfortable, small, and easy to use. Sensors for different parts of the body are simple to develop and construct out of low-cost silicone rubber materials. With this sensor system, it is possible to perform remote triage on a number of simultaneous casualties or monitor the physiological performance of an individual.

References

M.C. Baruch, *Wrist Sensor for Warfighter Status Monitor* (prototype development of the fiber optic coupler based heartbeat sensor with telecommunication capability), ARMY SBIR Phase II Contract DAMD17-96-C-6035, 1999

M.C. Baruch, *Physiographic Personnel Monitor* (fiber optic coupler based heartbeat sensor with telecommunication capability), DARPA TRP SBIR Phase I Contract DAMD17-96-C-6035, 1996

M.C. Baruch, D.W. Gerdt, C.A. Adkins, *Blood Pressure Determination based on Pulse Transit Time*, Serial Number F-9001B-PCT

D.W. Gerdt, M.C. Baruch, C.A. Adkins, *Fiber Optic Loop-back Sensor*, filed 8/24/98, USPTO Serial Number 60/097618

D.W. Gerdt, M.C. Baruch, C.A. Adkins, *Variable Fiber Optic Sensor and Sensing Apparatus using the Sensor*, filed 8/24/98, Serial Number F-9001A-PCT.

D.W. Gerdt, M.C. Baruch, C.A. Adkins, *Sensing Pad Assembly Employing Variable Coupler Fiberoptic Sensor*, Serial Number F-9001C-PCT

Appendix I

Technical Description of the Wrist Sensor System

The system allows wireless detection of pulse and breathing rate information from multiple test subjects as well as near real time pulse data for algorithm development and/or optimal sensor placement from individual test subjects. The system consists of multiple wireless sensor units and a receiver unit, connected to a personal computer. A Graphical User Interface (GUI) collects, stores, and displays the data provided by the sensor units. The system is comprised of two units: the Sensor Unit, worn on the wrist or other body pulse point, and the Receiver Unit, connected to the COM port of an IBM-compatible PC.

Sensor Unit Operation:

- Three modes of operation:

Idle Mode:

Any Sensor Unit in Idle Mode will transmit an "Idle" status message to the Receiver and "listen" for a new command once every 10 seconds. The sensor unit remains in a low power state to conserve battery life until it receives a Clinical Data Mode command or a Field Data Mode command. Idle Mode is the default mode of operation upon power up of the Sensor Unit.

Clinical Data Mode:

A Sensor Unit that is commanded into Clinical Data mode will acquire raw data at 512 samples per second and the internal digital temperature at 102.4 samples per second (every five raw samples a digital temperature sample is acquired). The data transmits to the receiver in packets consisting of five raw samples and one digital temperature sample. Data is transmitted and is received in between individual raw data samples. For each data packet there is one transmit and "listen" for an data acknowledge or an Idle command attempt and one retransmit attempt if no acknowledge or command was received. The Sensor Unit will remain in Clinical Data mode until it receives an Idle Mode command.

Field Data Mode:

A Sensor Unit that is commanded into Field Data mode will acquire raw data at 64 samples per second for 32 seconds and store the data to memory. Upon completion, the DSP processor is powered and converts the data from the time domain to the frequency domain and determines the pulse rate and breathing rate using its defined algorithm that was loaded from memory at DSP power-up. The results are stored back into memory along with a valid data flag. The DSP is then un-powered and two 16-bit values representing pulse rate and breathing rate are transmitted to the

receiver. If the DSP does not respond, the Sensor Unit will transmit a DSP Error message. There are six transmit and "listen" for a data acknowledge or an Idle Mode command attempts. The Sensor Unit will repeat the Field Data Mode data acquisition process until it receives an Idle Mode command.

Receiver Operation:

In Idle Mode

When the user has selected no modes of operation from the graphical user interface or upon system start up the Receiver Unit is instructed to command all sensors that it receives messages from to go into Idle Mode. All Idle Status messages that the Receiver Unit receives will be reported at the graphical user interface. This is the default mode at Receiver Unit power-up.

In Clinical Data Mode

When the user selects a Sensor Unit and requests Clinical data mode the Receiver Unit will only accept and acknowledge messages from the selected Sensor Unit. The Receiver Unit will ignore all other messages. The Receiver Unit will acknowledge all messages from the selected Sensor Unit with the Clinical Data Mode command and send the received data packets to the graphical use interface until the user requests a Clinical Data Mode stop command. NOTE: It is important for the user to ensure that a Sensor Unit that was in Clinical Data Mode respond back in Idle Mode before another Sensor Unit is commanded into Clinical Data Mode or Field Data Mode. If this is not done, a loss of data and/or communications may occur due to RF collisions.

In Field Data Mode

When the user selects Field Data Mode from the graphical user interface the Receiver Unit is instructed to command all Field Sensor Units that it has received Idle messages from to go into Field Data Mode. All Idle Status messages and Field Data messages that the Receiver Unit receives will be reported at the graphical user interface. The Receiver Unit will remain in this mode until the user requests the Stop Field Data Mode command at the graphical user interface.

Data:

Raw Data: 16 bit samples

Digital Temperature: 10 bit samples

Resolution: 0.25 C

Accuracy: +/- 2 C

Range: -55 C to +125 C

Hardware

The electronics unit of the Sensor Units consists of two cards interconnected by a control/data bus. The Network Card is used for communication and power control and the Front End used for data acquisition and calculations.

The Network Card:

Micro Controller: Microchip PIC16C67 (OTP Version) or the PIC16F877 (Flash Version) operating at 20MHz (divide by four internally for a 200nS instruction time).

Memory: 2 X 32KB EEPROM (dedicated data memory and dedicated DSP program memory)

Radio: 916.5MHz narrow band RF Transceiver operating at a raw data rate of 250Kbps. Manchester encoding is used to ensure a DC balanced signal.

The Front End Card:

Analog to Digital Converter: ADS8320 16 bit data acquisition. 13 Effective Number of Bits (ENOB).

Filtering: Two-pole (RF) low-pass filter, corner frequency at 22 kHz.

Gain: Transimpedance at 3.24 k Ω

Digital Signal Processor: Texas Instruments TMS320C5402 operating at internal frequency of 2.5MHz.

Appendix II

Operation Manual for the ETC Wrist Sensor System

In order to use the ETC wrist sensor(s) the software needed to communicate with the wrist unit must be installed on an IBM-compatible PC.

I. Installation of the software

The installation CD contains two software packages

- The ETC Wrist Sensor GUI version 1.05 will operate the wrist sensors in their data-streaming mode (at 512 Hz) only. The software shows three separate data graphs, one for the real-time data stream, as well as two others for real-time filtered data (one for the heartbeat frequency range, the other for the breathing rate range). The data graphs' vertical and time axes as well as the filter cut-ons and cut-offs can be adjusted on the fly. The data can also be saved to file continuously. This version of the software cannot access the DSP-based algorithm on the wrist sensor. *If the user wishes to use the DSP-based algorithm, the Invocon software version 2.0 needs to be loaded and utilized.* The capability to access the DSP will be implemented in the next software upgrade of the ETC Wrist Sensor GUI. However, *the same version of the DC-based algorithm is included with the software package itself and the same heartbeat and breathing rate determination can be accomplished* at the push of a button on the user interface.
- The BodyLAN™ software by Invocon version 2.0 allows operation of the wrist units in either the data-streaming mode (clinical mode) or the algorithm mode (field mode). The clinical mode displays the raw real-time data with no scale adjustment or filtering capability. The field mode displays only the results (actual rate number) for heartbeat and breathing rate on the GUI.

ETC Wrist Sensor Software Version 1.05

Installation of the ETC Wrist Sensor version 1.05 software:

- Find the folder "ETC Wrist Sensor vs. 1.05" on the CD and open it
- Click on the SETUP.exe file. The installation should commence
- After the installation, go to the C:\ root directory in the Windows Explorer
- Create a new directory called exactly "ETC Data". The streamed data from the wrist sensor will be stored here.
- Re-boot the computer after the installation is complete

The installation creates the BodyLAN subdirectory in the Program Files directory. The application file is WristSENSGUI.exe.

The program is be accessed from the Windows – Start – Programs menu under the heading: “ETC Wrist Sensor GUI” - ETC Wrist Sensor GUI, or by double-clicking the executable file given above.

Invocon BodyLAN™ Software version 2.0

Installation of the Invocon software:

- Find the folder “Invocon BodyLAN™ Software version 2.0” on the CD and open it
- Click on the SETUP.exe file. The installation should commence
- Re-boot the computer after the installation is complete

II. Using the wrist sensor system (with the ETC Wrist Sensor GUI software)

Note: It is recommended that the unit be handled only while the data stream is visualized on the PC monitor screen. This is to protect the sensitive fiber-optic coupler sensor located in the sensor housing and reduces the chance of inadvertently overdriving the sensor.

- Insert the tan-colored transceiver unit into a COM port of the computer.
- Launch the application either from the “ETC Wrist Sensor GUI” heading under the Windows – Start – Programs menu or by double-clicking the executable file WristSENSGUI.exe in the BodyLAN subdirectory of the Program Files directory.

The status window of the application appears. The window lists:

- *The ID numbers of active and selectable wrist sensors in the Idle Status window*
 - *The COM port the program is using to establish communication with the transceiver unit.*
 - *Provides a drop-down list Active Unit to select the wrist unit to receive data from*
- Flip the switch on the Wrist Sensor housing of one or more units to “On” to active the unit(s).

After a few seconds, the unit’s identification (unit ID #, idle status, date & time) appears in the Idle Status window.

- Clicking on the Active Unit drop-down list reveals the IDs of all available wrist units. Select a unit by clicking on it.



The unit's ID appears in the top remaining window of the Active Unit drop-down list and the Start Acquisition button enables.

- Click on the Start Acquisition button to initiate the data collection cycle.

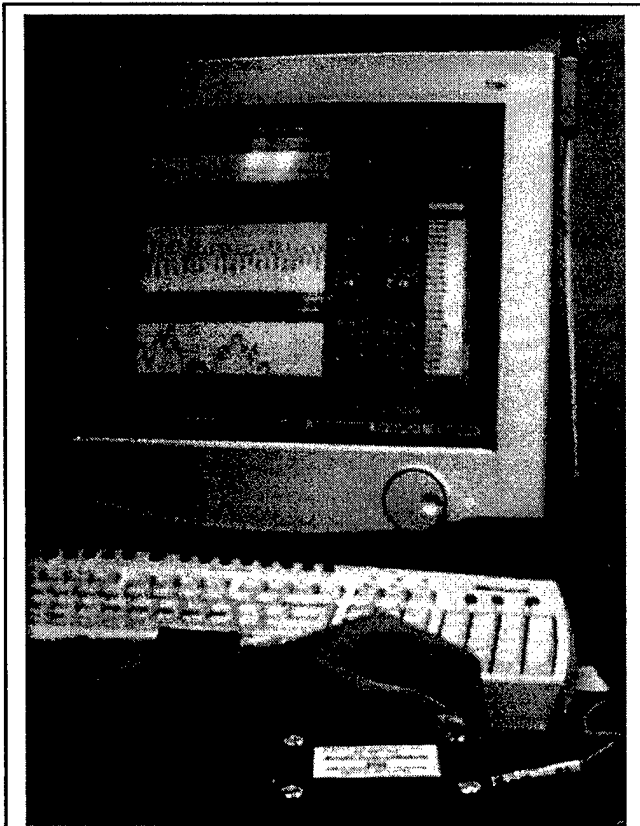
A new data acquisition window appears, displaying the raw data stream graph (top), as well as two others for real-time filtered data (one for the heartbeat frequency range, the other for the breathing rate range). The data graphs' vertical and time axis as well as the filter cut-ons and cut-offs are adjustable on the fly. If the check mark in the upper right corner is checked, the data is saved to a file, continuously

The heartbeat filter uses an FFT of a 4-second window data, updated every 0.5 seconds while the breathing filter, requiring a longer time window due to the low-frequency nature of the signal, uses a 16-second data window, updated every 0.5 seconds.

- *It may take up to 30 seconds for the data stream to appear in the top graph. If at that time, there is still no data stream, click on the Stop Acquisition button. This returns control to the previous window. Re-click on the Start Acquisition button, which returns control to the data acquisition window.*

On occasion, it may take several cycles until communication is established.

- *If the wrist sensor housing hose and the wristband hose are not already connected, connect them now by sliding the soft silicone tubing of the wristband over the harder vinyl hose of the sensor housing.*



Wrist Sensor System: Wrist unit & software GUI with raw data stream graph (top), heartbeat filter graph (center), and breathing filter graph (bottom).

Open the Pressure Relief Valve using a fingernail or pen. WHILE THE PRESSURE RELIEF VALVE IS OPEN, COMPLETELY DEPRESS THE SENSING PAD ON THE WRIST BAND. THEN, WHILE DEPRESSING THE SENSING PAD, RELEASE THE PRESSURE RELIEF VALVE.

The fact that the hydraulic system has been completely depressurized will be clear if, upon releasing the sensing pad, the sensing pad remains depressed due

to the slight vacuum that is established.

- *Now place the wristband on the wrist, making sure that the sensing pad is placed over the pulse point of the radial artery. Usually the best position has been right at the base of the hand.*

The signal stream visible in the GUI may at this point already be changing.

- *Pressurize the system by placing the thumb over the in-take hole of the bellows and pushing on the bellows while observing the signal on screen. The air pressure generated in the bellows has to be sufficient to temporarily open a one-way valve, which opens above a pressure of 1.5 psi, inside the housing. Therefore, while gentle pushing on the bellows is usually not sufficient to force air through the valve, short and quick "squirts" are very effective. It usually does not take more than a few "squirts" to see observable changes in the data stream.*

At this point, the heartbeat signal should be visible in the center data graph. The heartbeat signal starts 4 seconds after the raw data stream commences. Due to the default ac filter setting, the heartbeat signal is centered on the screen. The breathing filter graph will start displaying real-time data 16 seconds after commencement of the raw data stream.

Due to the characteristics of the fiber-optic coupler sensor, it is possible to obtain INVERTED heartbeat and breathing signals. This is not a malfunction of the device. The operational range of the sensor can be CAREFULLY examined by GENTLY pushing the sensing pad while observing the raw signal stream on-screen. If, while progressively pushing on the sensing pad, the on-screen signal increases, the heartbeat signal will be as expected. Further pushing will cause the on-screen signal to TURN OVER and decrease. If the pneumatic system is pressurized such that the sensor operates in this range, the physiological signal will be inverted.

- *Algorithm Use: the algorithm for determining heartbeat and breathing rate is part of the ETC Wrist Sensor GUI software and can be activated from the front panel by pushing the Algorithm button. After 32 seconds, the results are displayed in the panels above the button. While this algorithm is identical to the one programmed into the DSP located on the Wrist Sensor, it resides as part of the ETC software on the PC, not the DSP.*
- *Removing the wrist band from the wrist:*
 - *Open the Pressure Relief Valve using a fingernail or pen. If necessary, deflate the pneumatic system further by pushing on the wristband on the backside of the sensing pad.*

- Remove the wristband from the wrist and flip the switch on the sensor housing to "off".

III. Using the Wrist Sensor System (with the Invocon BodyLAN™ Software vs 2.0)

Since operation of the Wrist Sensor System with the Invocon 2.0 software is essentially identical to operation of the ETC Wrist Sensor GUI software, it is recommended that the above description be read first, since the instructions presented here will only identify the differences in the software operation.

- Launch the Invocon software (" C:\Program Files\BodyLAN 2.0\BodyLAN.exe ", or from Start – Programs - BodyLAN menu)

A similar status window as before appears. The window lists:

- The ID numbers of active and selectable wrist sensors in the Idle Status window
 - The COM port the program is using to establish communication with the transceiver unit.
 - Provides a drop-down list Active Unit to select the wrist unit to receive data from
 - Provides two mode buttons: One is for the clinical (streaming) and the other is for the field (algorithm) mode.
- ***If the Field Mode is to be used, NONE of the Wrist Sensor units identified in the Idle Status window should be selected under Active Unit.***

All units identified in the Idle Status window will be put in Field Mode simultaneously and will begin reporting heartbeat and breathing results after about 32 seconds and thereafter in intervals of 32 seconds. A similar status window as before appears. The window lists:

- *In order to change from one mode to another, the Stop Current Mode button must be pressed.*

All units identified in the Idle Status window must return to the idle status before being commanded into a new mode.

- In order to select a unit for Clinical Mode operation, click on the Active Unit drop-down list that reveals the IDs of all available wrist units. Select one and only one unit by clicking on it.
- Click on the Start Clinical Mode button.

The Idle Status window disappears. A graphical window now appears that, once communication commences, shows the real-time data stream. No scale adjustments or filtering is possible.